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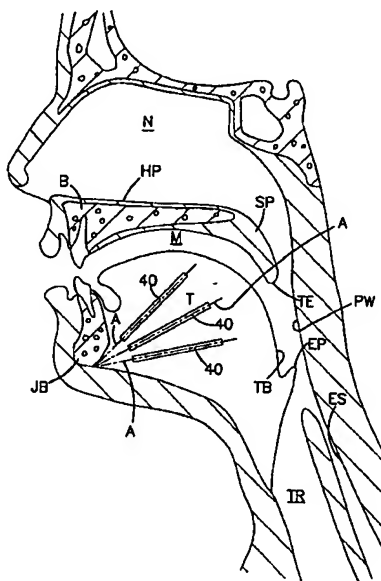
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[Continued on next page]

(54) Title: AIRWAY IMPLANT



(57) Abstract: A method and apparatus are disclosed for treating a condition of a patient's airway. The condition is attributed at least in part to a spacing of tissue from opposing surfaces in the airway. In one embodiment, the method and apparatus include placing a tissue contractor within the tissue. The contractor includes a static end (16) and a tissue in-growth engaging end (14). The static end is secured to a bony structure adjacent to tissue to be contracted. The tissue in-growth engaging end is secured to the tissue and spaced from the bony structure. A spacing between the tissue engaging end and a bony end is contracted in order to place the tissue under tension.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

AIRWAY IMPLANT

This application is being filed as a PCT patent application in the name of
5 Restore Medical, Inc., a U.S. national corporation, claiming priority to U.S. patent
application 10/698,819 filed 31 October 2003.

I.

BACKGROUND OF THE INVENTION

1. Field of the Invention

10 This invention pertains to a method and apparatus for treating a condition of
an upper airway of a patient. More particularly, this invention is directed to such a
method and apparatus including an implant to improve patency of the airway.

2. Description of the Prior Art

15 Upper airway conditions such as obstructive sleep apnea ("OSA") and snoring
have received a great deal of attention. These conditions have recognized
sociological and health implications for both the patient and the patient's bed partner.

Numerous attempts have been made towards treating OSA and snoring. These
include placing implants in either the tissue of the soft palate or the pharyngeal airway
20 as disclosed in commonly assigned U.S. Pat. No. 6,250,307 to Conrad et al. dated
June 26, 2003, U.S. Pat. No. 6,523,542 to Metzger et al. dated February 25, 2003 and
U.S. Pat. No. 6,431,174 to Knudson et al. dated August 13, 2002. Further, U.S. Pat.
No. 6,601,584 to Knudson et al. dated August 5, 2003 teaches a contracting implant
for placement in the soft palate of the patient.

25 In the '584 patent, an embodiment of the contracting implant includes two
tissue attachment ends (for example ends 102b in Figs. 46 and 47) which are

maintained in a space-apart, stretched relation by a bio-resorbable member 102c which surrounds an internal spring or resilient member 102a. After implantation, tissue grows into the attachment ends 102b. The bioresorbable member 102c is selected to resorb after the tissue in-growth permitting the resilient member 102a to contract drawing ends 102b together as illustrated in Fig. 47 of the '584 patent (incorporated herein by reference). Tissue contraction is believed to be desirable in that the tissue contraction results in a debulking of the tissue and movement of tissue away from opposing tissue surfaces in the pharyngeal upper airway.

Another prior art technique for treating OSA or snoring is disclosed in U.S. Pat. No. 5,988,171 to Sohn et al. dated November 23, 1999. In the '171 patent, a cord (e.g., a suture material) (element 32 in Fig. 6 of the '171 patent) is placed surrounding a base of the tongue and secured to the jaw by reason at an attachment member (element 20 in Fig. 6 of the '171 patent). In the method of the '171 patent, the member 32 can be shortened to draw the base of the tongue toward the jaw and thereby move the tissue of the base of the tongue away from the opposing tissue of the pharyngeal airway. However, this procedure is often uncomfortable. This procedure, referred to as tongue suspension, is also described in Miller et al., "Role of the tongue base suspension suture with The Repose System bone screw in the multilevel surgical management of obstructive sleep apnea", Otolaryngol. Head Neck Surg., Vol. 126, pp. 392 – 398 (2002).

Another technique for debulking tissue includes applying radio frequency ablation to either the tongue base or of the soft palate to debulk the tissue of the tongue or palate, respectively. This technique is illustrated in U.S. Pat. No. 5,843,021 to Edwards et al. dated December 1, 1998. RF tongue base reduction procedures are described in Powell et al., "Radiofrequency tongue base reduction in sleep-disordered

breathing: A pilot study”, Otolaryngol. Head Neck Surg., Vol. 120, pp. 656 – 664 (1999) and Powell et al., “Radiofrequency Volumetric Reduction of the Tongue – A Porcine Pilot Study for the Treatment of Obstructive Sleep Apnea Syndrome”, Chest, Vol. 111, pp. 1348 – 1355 (1997).

5 A surgical hyoid expansion to treat OSA is disclosed in U.S. Pat. No. 6,161,541 to Woodson dated December 19, 2000. Other tongue treatments for OSA include stimulation of the hypoglossal nerve. This procedure is described in Eisle et al., “Direct Hypoglossal Nerve Stimulation in Obstructive Sleep Apnea”, Arch. Otolaryngol. Head Neck Surg., Vol. 123, pp. 57 – 61 (1997).

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II.

SUMMARY OF THE INVENTION

According to a preferred embodiment to the present invention a method and apparatus are disclosed for treating a condition of a patient’s airway. The condition is
15 attributed at least in part to a spacing of tissue from opposing surfaces in the airway. In one embodiment, the method and apparatus include placing a tissue contractor within the tissue. The contractor includes a static end and a tissue in-growth engaging end. The static end is secured to a bony structure adjacent to tissue to be contracted. The tissue in-growth engaging end is secured to the tissue and spaced from the bony
20 structure. A spacing between the tissue engaging end and a bony end is contracted in order to increase the airway geometry.

25

III.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side elevation, schematic view of a patient illustrating structure defining an upper airway of the patient and showing an implant according to an
5 embodiment of the present invention positioned within the soft palate and secured to the bony structure of a hard palate and showing a similar implant in the tongue and secured to the bony structure of the jaw;

Fig. 2 is the view of Fig. 1 following contracting of the implants in the palate and tongue;

10 Fig. 3 is a view similar to that of Fig. 1 and showing an alternative embodiment of the present invention with implants of the alternative embodiment implanted in both the soft palate and tongue;

Fig. 4 is the view of Fig. 3 showing the implants in a contracted state;

15 Fig. 5 is a view similar to that of Fig. 1 and showing a further alternative embodiment of the present invention with an implant of the further alternative embodiment implanted in the tongue;

Fig. 6 is the view of Fig. 5 contraction of tissue around the implant;

Fig. 7 is a top plan view of Fig. 5 showing an anterior-posterior axis A-P of the tongue;

20 Fig. 8 is a view similar to that of Fig. 1 and showing a yet further alternative embodiment of the present invention with an implants of the yet further alternative embodiment implanted in the tongue;

Fig. 9 is a view similar to Fig. 7 showing immediate post-implant of a still further embodiment of the present invention; and

Fig. 10 is the view of Fig. 9 following tissue in-growth and resorption of bio-resorbable elements.

IV.

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DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference now to the various drawing figures in which identical elements are numbered identically throughout, a description of the preferred embodiment of the present invention will now be provided. To facilitate a description and an understanding of the present invention, the afore-mentioned U.S. Pat. Nos. 6,250,307; 10 6,523,542; 6,431,174; 6,601,584; 5,988,171 and 5,843,021 are hereby incorporated herein by reference.

With initial reference to Fig. 1, a soft palate SP is shown in side elevation view extending from a bony portion of a hard palate HP. The soft palate SP extends rearward to a trailing end TE. Fig. 1 also illustrates a tongue T with a base TB 15 opposing a pharyngeal wall PW. A jawbone JB is shown at the lower front of the tongue T.

As a first described embodiment of the present invention, an implant 10 is shown in Fig. 1 completely implanted within the tongue T. A similar implant 10' is fully implanted in the soft palate SP. As will be apparent, implants 10, 10' are 20 functionally and structurally similar differing only in size to facilitate placement in the tongue T and soft palate SP, respectively. As a result, a description of implant 10 will suffice as a description of implant 10' (with similar elements similarly numbered with the addition of an apostrophe to distinguish the implants 10, 10'). Further, while both implants 10, 10' are shown implanted in the same patient, either could be separately 25 implanted.

The implant 10 includes an elongated member 12 having a tissue in-growth end 14 and a static end 16. The tissue in-growth end 14 may be any tissue growth inducing material (e.g., felt or PET) to induce growth of tissue into the end 14 to secure the end 14 to surrounding tissue following implantation. The elongated member 12 may be suture material one end secured to the felt 14 and with the static end 16 being a free end of the suture material 12.

An anchor 18 (in the form of a treaded eye-bolt) is secured to the jawbone JB. In the case of implant 10', the anchor 18' is secured to the bone of the hard palate. The end 16 is secured to the anchor 18.

10 The end 14 is placed in the tongue near the tongue base TB. A surgeon adjusts a tension of the suture 12. This causes the tongue base TB to be urged toward the jawbone JB thereby placing the tissue of the tongue in compression. When a desired tension is attained, the surgeon may tie off the static end 16 at the bolt 18 retaining the tissue of the tongue T under tension. This method and apparatus
15 provides a resistance to movement of the tongue base TB toward the pharyngeal wall PW. Similarly, with implant 10', the trailing end TE of the soft palate SP is urged away from the back of the throat and the soft palate SP is prevented from lengthening.

Placing the implants 10, 10' under tension as in Fig. 1 provides therapy in that the tongue base TB and soft palate trailing end TE are retained from movement
20 toward the pharyngeal wall PW. In addition, at time of initial implantation or thereafter, a surgeon may obtain access to anchors 18, 18' and further shorten the length of the elongated member 12 (i.e., by pulling the member 12 through the bolt 18, 18') to draw the tongue base or trailing end away from the pharyngeal wall to a new profile. This is illustrated in Fig. 2 with the contracted profile shown in solid

lines TB, TE and contrasted with the original profile shown in phantom lines TB', TE'.

Referring to Figures 3 and 4, an alternative embodiment of the present invention is shown as a implant 10a for the tongue T or implant 10a' for the soft palate SP. As with the embodiments of Figs. 1 and 2, implants 10a, 10a' are functionally and structurally similar differing only in size to facilitate placement in the tongue and soft palate, respectively. As a result, a description of implant 10a will suffice as a description of implant 10a' (with similar elements similarly numbered with the addition of an apostrophe to distinguish the implants 10a, 10a'). Further, both implants 10a, 10a' are shown implanted in the same patient. Either or both implants could be implanted.

Implant 10a includes a tissue engaging end 14a and static end 16a. As in the embodiment of Fig. 1, the static end 16a is secured to a hard palate at the eyelet of an eyebolt 18a secured to the jawbone JB. Again, as in the embodiment of Fig. 1, the tissue-engaging end 14a may be any material which encourages tissue in-growth and attachment to tissue. An example of such a material may be PET or a felt material.

The tissue engaging end 14a and the static end 16a are connected by a resilient elongated member 12a which may be in the form of a spring member such as nitinol or other member which may be stretched to create a bias urging ends 14a, 16a toward one another. Opposing the bias of the spring member 12a is a bioresorbable material positioned between the tissue-engaging end 14a and the bolt 18a.

After placement of the implant 10a within the tissue of the tongue and with the end 14a near the tongue base TB, the bio-resorbable material 20 will later resorb into the tissue of the tongue T permitting end 14a to be urged toward bolt 18a by the resilience of the spring 12a. This is illustrated in Fig. 4, where the contracted implant

10a places the tissue of the tongue under tension and urging the tongue base TB away from the pharyngeal wall PW. In Fig. 4, the contracted profile of the tongue base TB (and soft palate trailing end TE) is shown in solid lines and the original profile TB' (TE') is shown in phantom lines.

5 Figs. 5 – 7 illustrate a still further embodiment for reducing the tongue base TB. In this embodiment, a sheet 30 of tissue in-growth material (e.g., a sheet of felt with numerous interstitial space) is place in the tongue near the base TB. The sheet 30 is placed beneath the tongue surface and parallel to the base TB substantially covering the area of the tongue base TB. Scarring from the material contracts over
10 time resulting in a reduction in the tongue base as illustrated in Fig. 6. To heighten the amount of tongue base reduction, the sheet 30 may be impregnated with a tissue reducing agent (e.g., a sclerosing agent).

 Figs. 9 and 10 illustrate a further variant of Figs. 5 – 7. The implant 50 includes three tissue in-growth pads 61, 62, 63. A nitinol bar 64 connects the pads 61
15 – 63 in-line with pad 63 centrally positioned. The bar 64 is pre-stressed to have a central bend shown in Fig. 10. Bio-resorbable sleeves 65, 66 hold the bar 64 in a straight line against the bias of bar 64 as in Fig. 9. The implant 50 is implanted as shown in Fig. 9 with the straight bar 64 parallel to the tongue base TB. After
implantation, tissue grows into pads 61 – 63. After the time period of in-growth, the
20 sleeves resorb as in Fig. 10. With the sleeves resorbed, the bar 64 bends to its pre-stressed shape. The tongue base moves with the pad 63 to reposition the tongue base (illustrated in Fig. 10 as the shift from TB' to TB).

 Fig. 8 illustrates a still further embodiment of the invention for reducing the tongue base. Certain muscles of the tongue (particularly, the genioglossus muscles)
25 radiate from the jawbone JB to the tongue surface as illustrated by lines A in Fig. 8.

Contacting implants 40 identical to those in Figs. 46 and 47 of U.S. Pat. No. 6,601,584 are placed with a contracting axis (the axis between tissue in-growth ends 14a' – identical to ends 102b in Figs. 46, 47 of the '584 patent) are placed in the tongue in-line with the muscle radiating lines A. Alternatively, the contracting
5 implant 40 may be of the construction shown in Figs. 48 and 49 of the '584 patent. As the implants contract over time, they urge the tongue from collapsing toward the pharyngeal wall. In lieu of contracting implants, the elongated implants can be static implants such as implants shown in Fig. 11 of U.S. Pat. No. 6,250,307 and labeled 20.

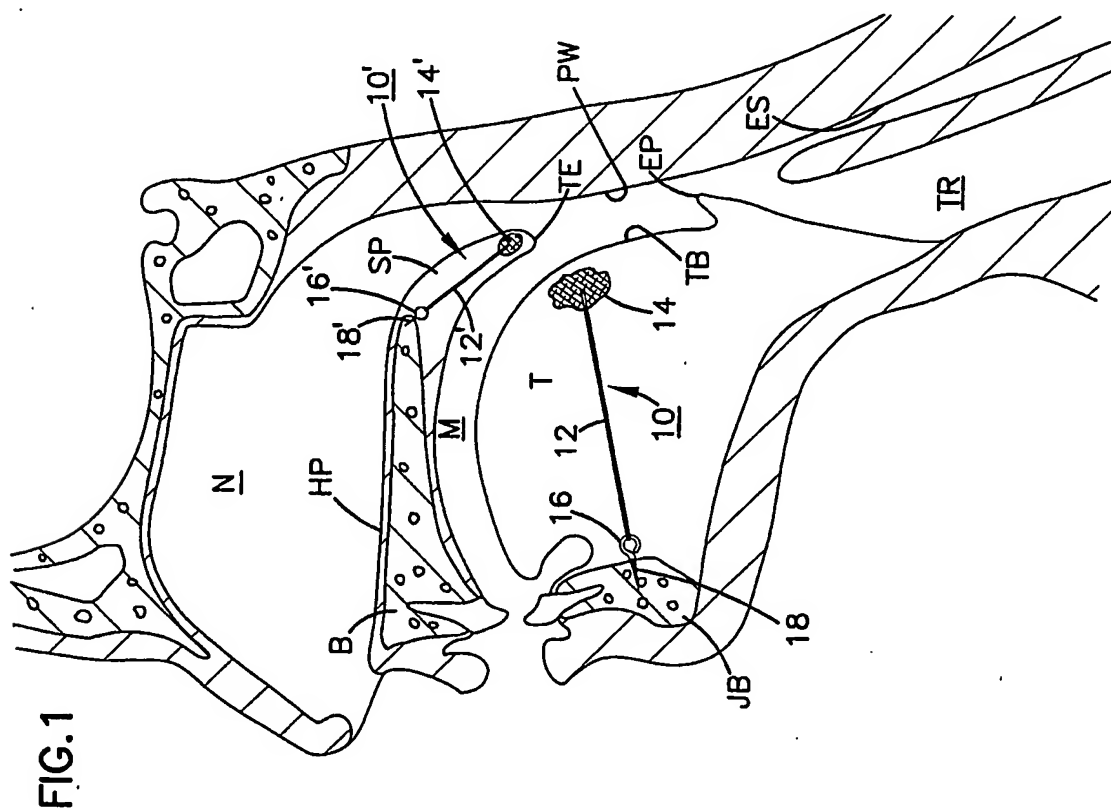
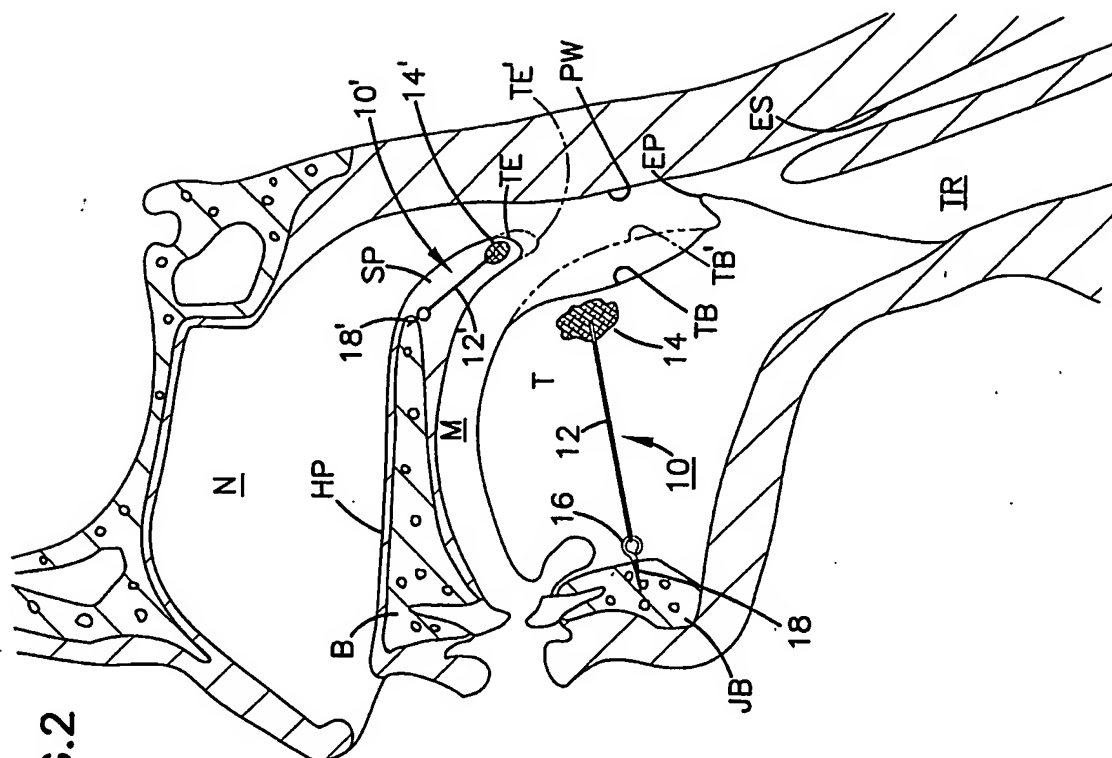
The foregoing describes numerous embodiments of an invention for an
10 implant for the tongue and soft palate to restrict tissue movement toward the pharyngeal wall. Having described the invention, alternatives and embodiments may occur to one of skill in the art. It is intended that such modifications and equivalents shall be included within the scope of the following claims.

What is claimed is:

1. A method for treating a condition of a patient's airway wherein said condition is attributed at least in part to a spacing of a tissue from opposing surfaces in said airway; said method comprising:
 - placing a tissue contractor within said tissue within an upper airway of said patient, said contractor including a static end and a tissue-engaging end;
 - securing said static end to a bony structure adjacent said tissue and securing said tissue-engaging end to said tissue and spaced from said bony structure;
 - contracting a spacing between said tissue-engaging end and bony structure.
2. A method according to claim 1 wherein said contracting includes shortening a length of said contractor between tissue-engaging end and said static end after at least partially securing said tissue-engaging end to said tissue.
3. A method according to claim 2 wherein said shortening includes pulling on said contractor near said bony structure and securing said contractor to said bony structure at said static end with said tissue under tension.
4. A method according to claim 2 wherein said shortening includes securing said contractor to said bony structure at said static end and then contracting a spacing between said tissue-engaging end and said static end to create a tension in said tissue.
5. A method according to claim 4 wherein said contractor includes a tensioning member between said static end and said tissue-engaging end with said tensioning member retained in a stretched state by a bio-resorbable member selected to resorb after placement of said contractor in said tissue.
6. A method according to claim 1 wherein said tissue is a soft palate of said patient and said bony structure is a hard palate of said patient.
7. A method according to claim 1 wherein said tissue is a tongue of said patient and said bony structure is a jaw of said patient.

8. A method according to claim 1 wherein said condition is snoring.
9. A method according to claim 1 wherein said condition is sleep apnea.
10. An apparatus for treating a condition of a patient's airway wherein said condition is attributed at least in part by a spacing of a tissue from opposing surfaces in said airway; said apparatus comprising:
 - a tissue contractor dimensioned so as to be placed within said tissue within an upper airway of said patient, said contractor including a static end and a tissue-engaging end;
 - said static end adapted to be secured to a bony structure adjacent said tissue;
 - said tissue-engaging end adapted to secure to said tissue;
 - said contractor adapted to contract a spacing between said tissue-engaging end and said bony structure.
11. An apparatus according to claim 10 comprising an attachment for securing said static end to said bony structure after pulling on said contractor near said bony structure and securing said contractor to said bony structure at said static end with said tissue under tension.
12. An apparatus according to claim 10 wherein said contractor has a spacing between said tissue-engaging end and said static end which is reducible after said tissue-engaging end is secured to said tissue to create a tension in said tissue.
13. An apparatus according to claim 12 wherein said contractor includes a tensioning member between said static end and said tissue-engaging end with said tensioning member retained in a stretched state by a bio-resorbable member selected to resorb after placement of said contractor in said tissue.
14. An apparatus according to claim 10 wherein said tissue is a soft palate of said patient and said bony structure is a hard palate of said patient.
15. An apparatus according to claim 10 wherein said tissue is a tongue of said patient and said bony structure is a jaw of said patient.

16. An apparatus according to claim 10 wherein said condition is snoring.
17. An apparatus according to claim 10 wherein said condition is sleep apnea.
18. A method for treating a condition of a patient's airway wherein said condition is attributed at least in part to a spacing of a base of a tongue from opposing surfaces of a pharyngeal wall of said airway; said method comprising:
 - placing a tissue contractor within said tongue in close proximity to said base of said tongue, said contractor selected to induce a contracting fibrosis to a material of said contractor.
19. A method for treating a condition of a patient's airway wherein said condition is attributed at least in part to a spacing of a base of a tongue from opposing surfaces of a pharyngeal wall of said airway; said method comprising:
 - placing an implant within said tongue in close proximity to said base of said tongue, said implant have a relaxed shape and an implanted shape and having tissue in-growth areas;
 - implanting said implant for tissue to fix to said implant at a plurality of points and reshape said tongue base after re-shaping of said implant to said rest shape.
20. A method for treating a condition of a patient's airway wherein said condition is attributed at least in part to a spacing of a base of a tongue from opposing surfaces of a pharyngeal wall of said airway; said method comprising:
 - placing a tissue contractor within said tongue with a contracting axis of said contractor aligned with an axis of a genioglossus muscle.



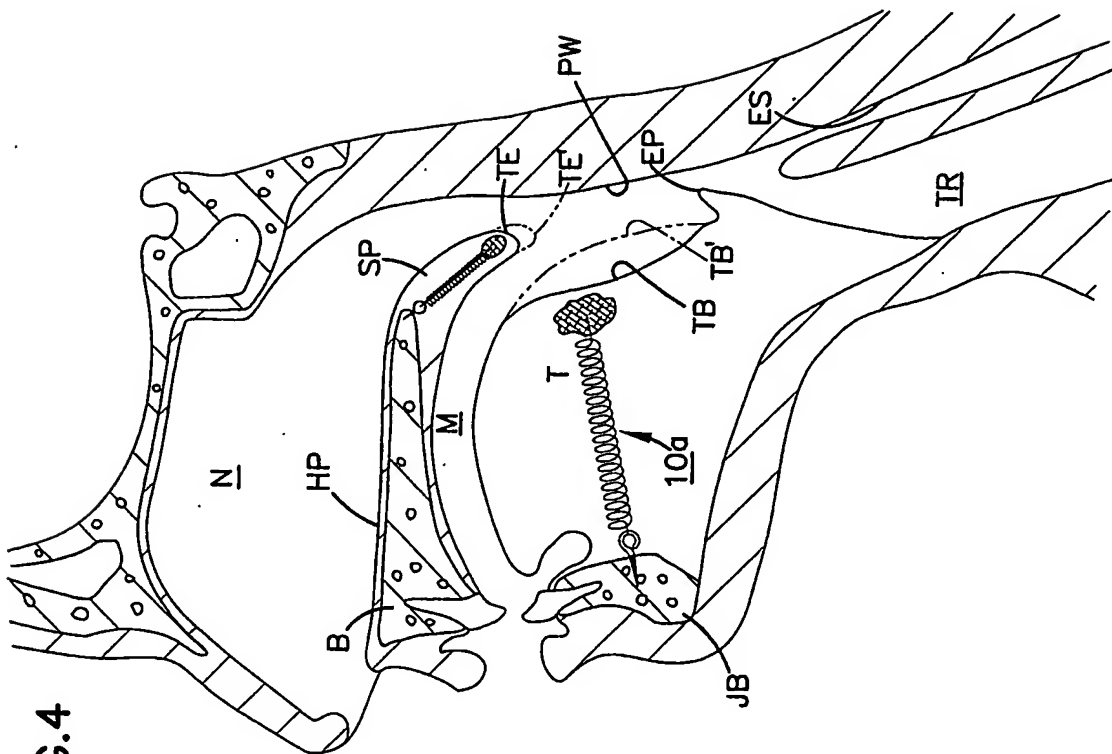


FIG. 4

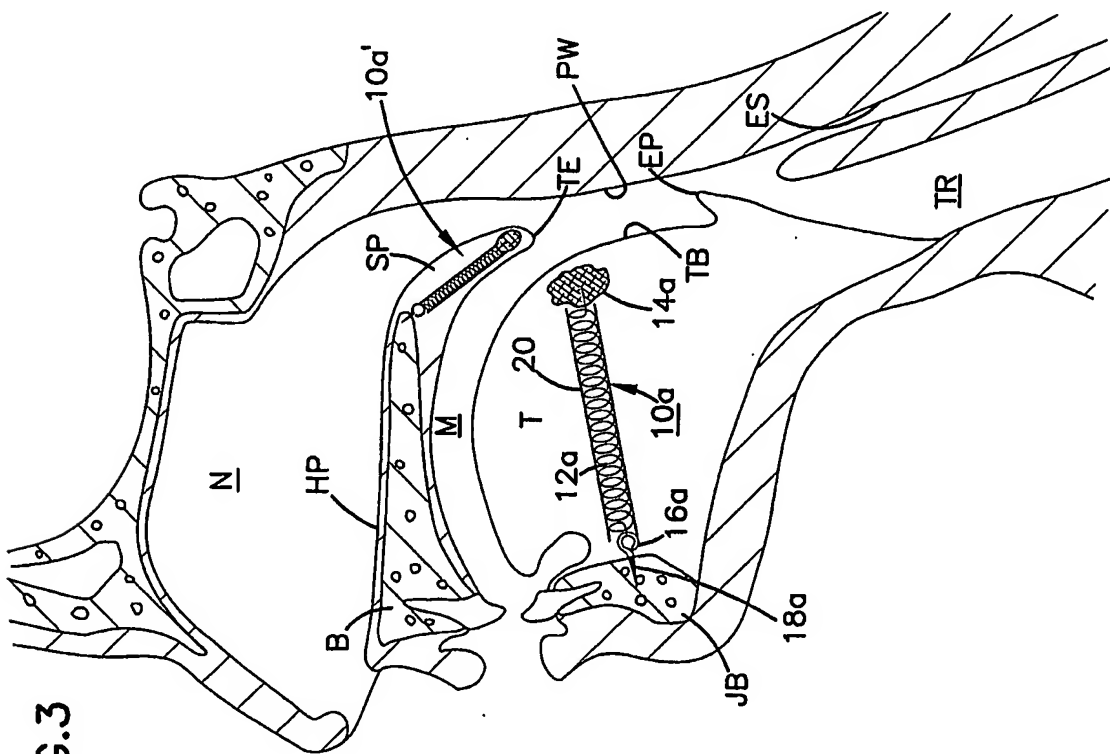


FIG. 3

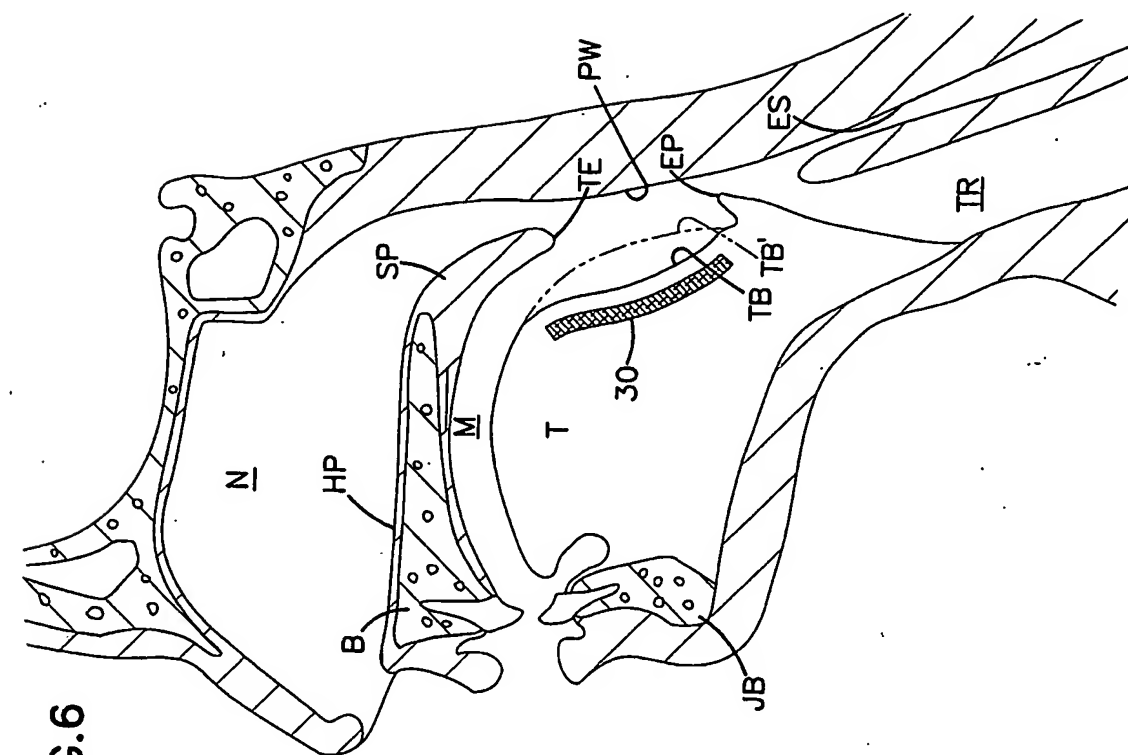


FIG. 5

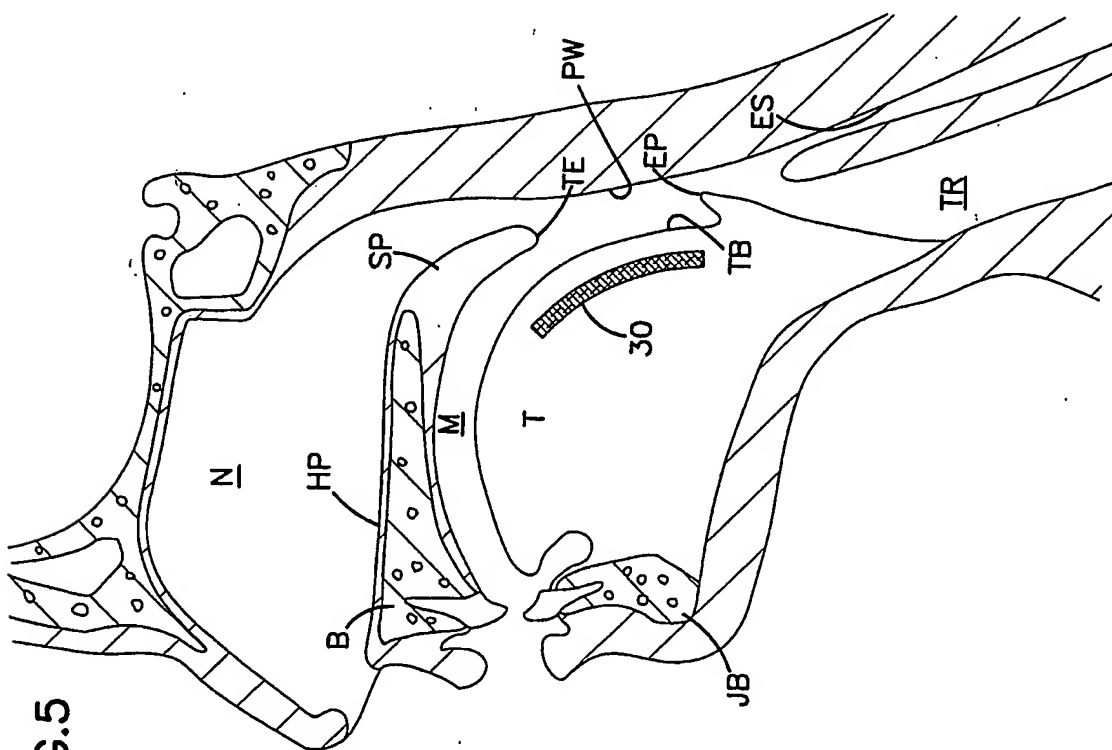
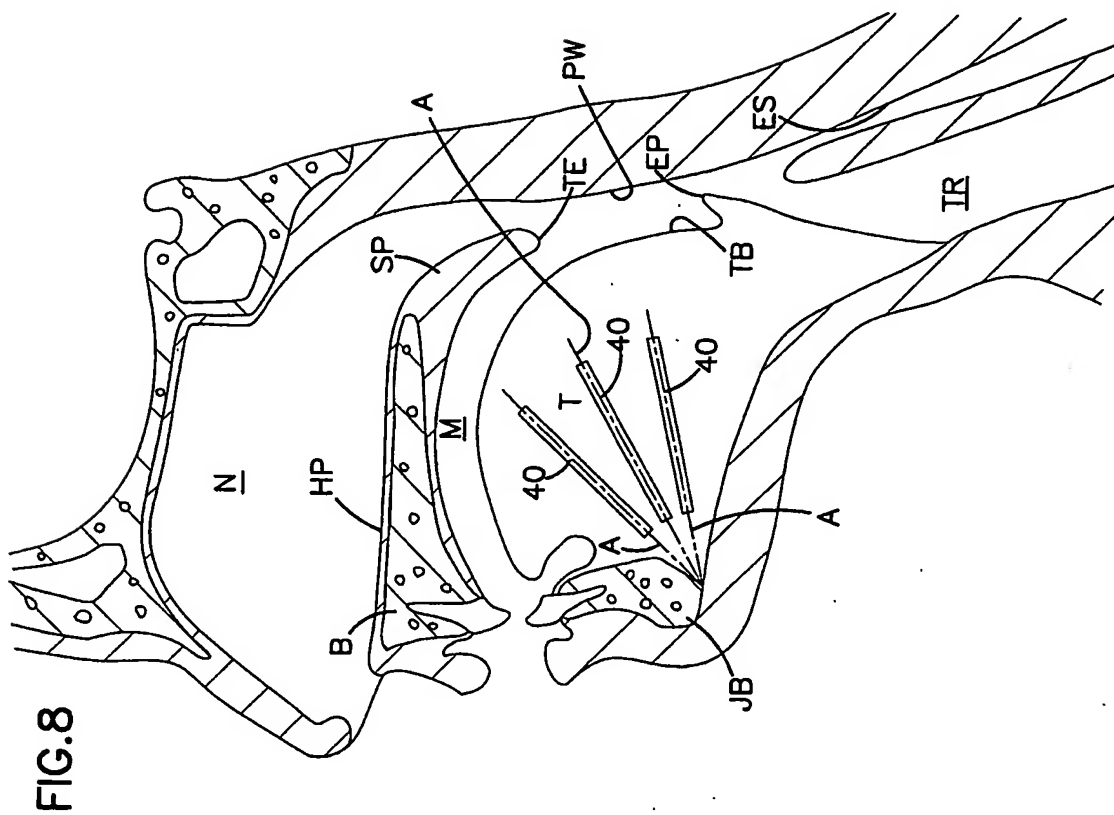
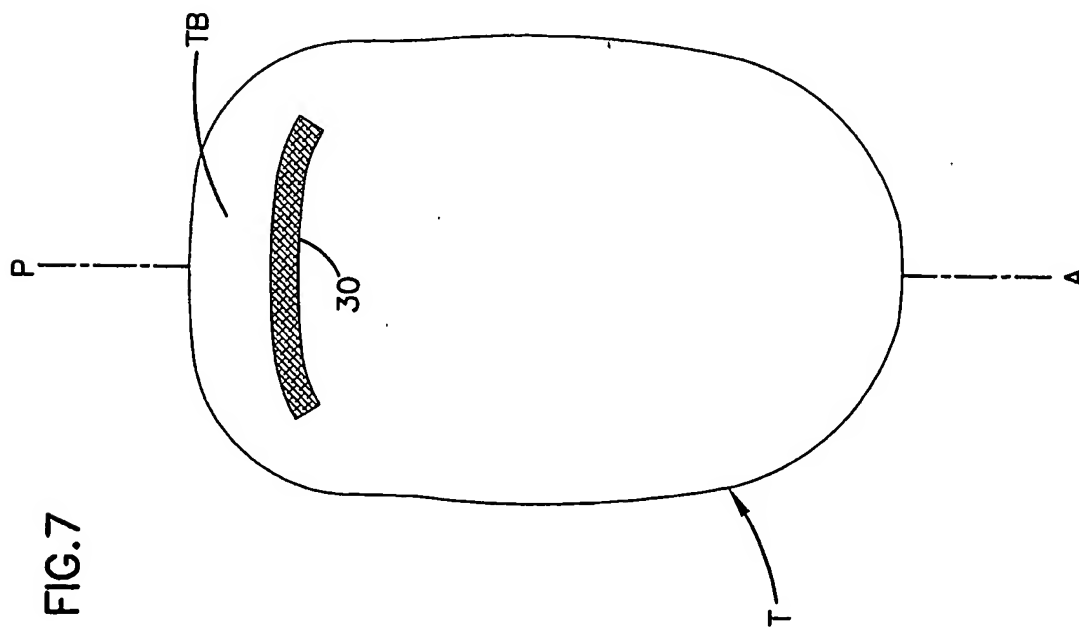
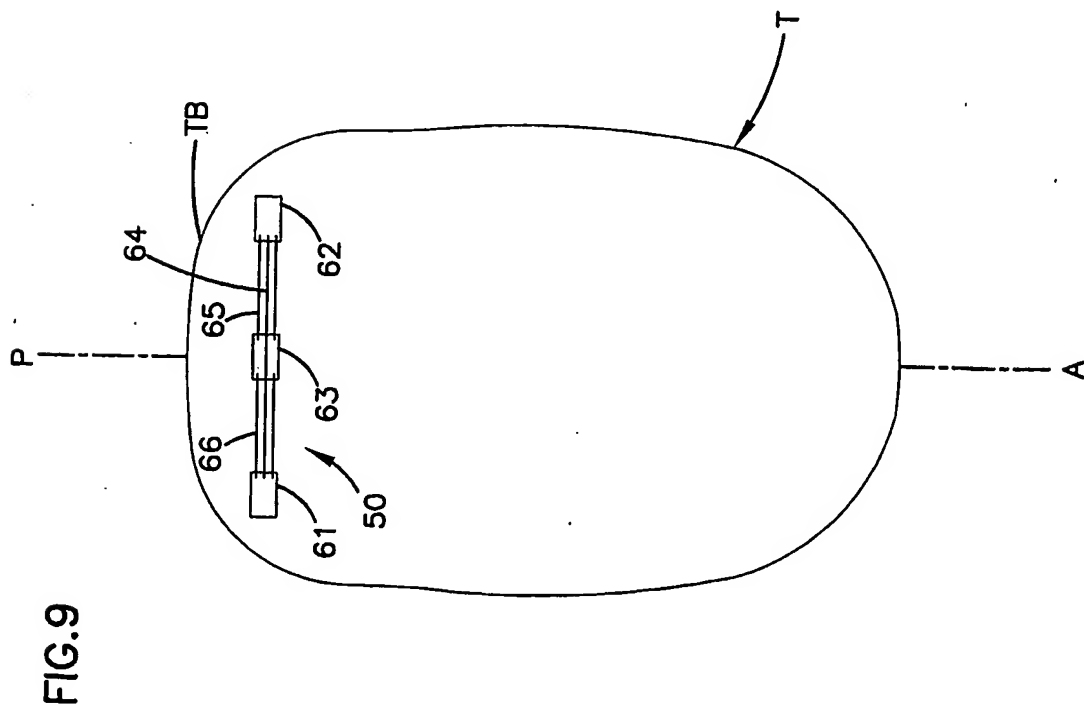
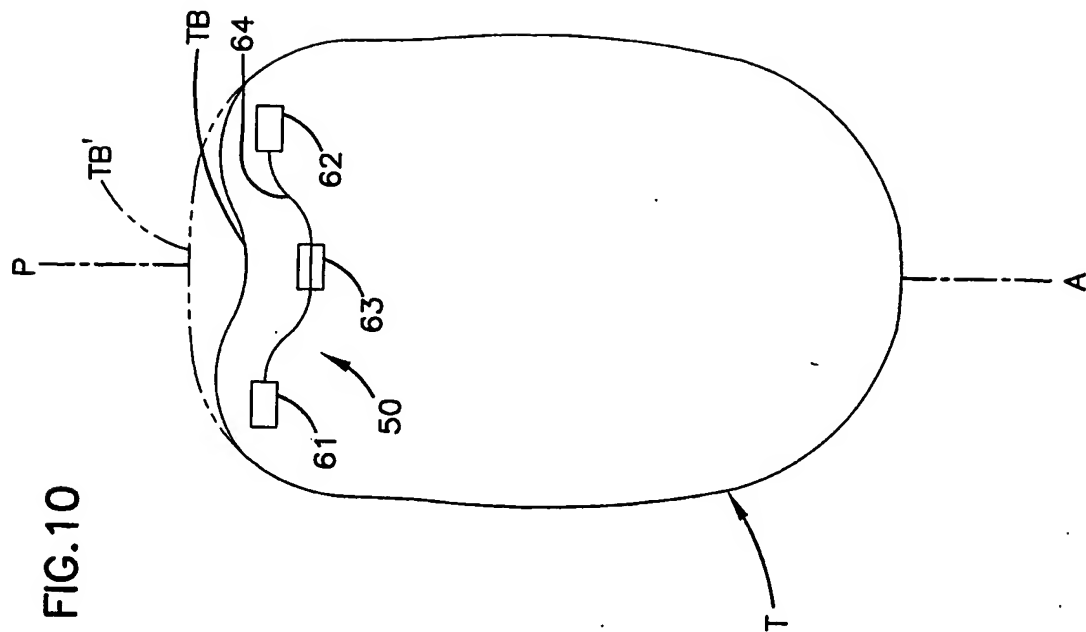


FIG. 6





INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/031066

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F5/56

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 199 20 114 A1 (FEGE, WOLFGANG) 9 November 2000 (2000-11-09) figure 1 column 3, line 49 - line 53 column 3, line 63 - column 4, line 2 claim 3	10-12, 14,16,17
Y		13
X	US 5 988 171 A (SOHN ET AL) 23 November 1999 (1999-11-23) cited in the application figures 6,9A-9E column 1, lines 8,9 column 6, line 1 - line 8 column 7, line 6 - line 43	10-12, 15-17
Y		13

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the International filing date but later than the priority date claimed

- *T* later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *G* document member of the same patent family

Date of the actual completion of the International search

24 January 2005

Date of mailing of the International search report

01/02/2005

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

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Application No

PCT/US2004/031066

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2001/050084 A1 (KNUDSON MARK B ET AL) 13 December 2001 (2001-12-13) figures 45-47 paragraph '0104!	13
A	US 6 408 851 B1 (KARELL MANUEL L) 25 June 2002 (2002-06-25) figures 1,1A	10-17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/031066

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-9, 18-20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int:
nal Application No
PCT/US2004/031066

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